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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/056,524 | 01/23/2002 | Thomas Hofmann | 3818.01-1 | 4336 |

7590 04/22/2004

HANA VERNY
PETERS, VERNY, JONES & SCHMITT, LLP
SUITE 6
385 SHERMAN AVENUE
PALO ALTO, CA 94306

| EXAMINER | |
|---|---|
| GOLLAMUDI, SHARMILA S | |
| ART UNIT | PAPER NUMBER |
| 1616 | |

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/056,524 | HOFMANN, THOMAS | |
| | Examiner | Art Unit | |
| | Sharmila S. Gollamudi | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *02 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23,25,26,28 and 29* is/are pending in the application.

4a) Of the above claim(s) *27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23,25,26,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Receipt of Amendments filed on January 2, 2004 and Change of Address filed March 4, 2004 is acknowledged. Claims 30-37 are cancelled. Claim 27 is withdrawn. Claims 1-23, 25-26, and 28-29 are pending in this application.

### *Election/Restrictions*

Applicant's election with traverse of species is acknowledged. The traversal is on the ground(s) that all the claims were examiner prior to the filing of the Request of Continued Examination. It is pointed out that when an applicant files an RCE, it is similar to filing a new case and restriction practice may be applied. It is also pointed out that a restriction requirement may be made at any point during prosecution as long as the examiner shows undue burden. Additionally it is pointed out that the requirement in the last office action was a species requirement not a restriction, thus, if the generic claims are found to be allowable, then the applicant is entitled to the additional species. The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**The rejection of claims 25-26 and 29 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating snoring, sleep apnea or sudden infant death syndrome, does not reasonably provide enablement for preventing snoring, sleep apnea or sudden infant death syndrome is maintained.**

**The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.**

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, state of the art, guidance of the specification, predictability if the art, and the working examples. All the factors have been considered with regard to the claim, with the most relevant factors discussed below.

**Nature of the Invention:** The claim is drawn to a method of treating or preventing snoring, sleep apnea or sudden infant death syndrome. The nature of the invention is complex in that it encompasses the prevention of snoring or sleep apnea with the instant compound such that an individual never has the instant respiratory disorder.

**Breadth of Claims:** The complex nature of the claim is greatly exacerbated by the breadth of the claim. The claim encompasses the prevention of snoring, sleep apnea, and SIDS and the actual cause of the disorders are due to several factors, i.e. age, sex, obesity, upper airway structural abnormalities, etc. This may or may not be addressed by the administration of the composition.

**State of the Art:** While the state of the art recognizes alleviation of the disorders with the use of synthetic surfactants, the connection between the actual cause of the disorder and the prevention of the disorder itself has not been established. The state of the art recognizes the treatment of the symptoms of the disorder may be through the

administration of alkylaryl polyether alcohol. For instance, the actual cause of SIDS in the art is not known, many possible theories exist in the art.

**Guidance of the Specification**: The guidance given by the specification as to how one would administer the claimed composition in order to actually prevent the disease is minimal. All the guidance provided by the specification is directed towards the treatment rather than the prevention of snoring, sleep apnea, and SIDS. For instance, the actual prevention of snoring is not demonstrated, rather the treatment is with continued administration of the instant compound, snoring is treated. However, the actual cause and cure of the snoring is not addressed.

**Predictability of the Art:** The lack of significant guidance from the specification or prior art with regard to the actual prevention of the disorders in a human subject with the administration of the instant composition makes practicing the claimed invention unpredictable in terms of the prevention of the disorder.

**Working Examples:** All the working examples provided by the specification are directed toward the treatment rather than the prevention of the disorder.

For the stated reasons above, the rejection based on enablement is deemed proper.

***Response to Arguments***

Applicant argues that the prevention and treatment, especially of snoring, is the same thing.

Applicant's arguments have been fully considered but they are not persuasive. The examiner acknowledges the amendments made to the method claims removing the

word "preventing" and therefore the 112, first paragraph rejection pertaining to these claims is withdrawn. However, the composition claim still recite the word "preventing" and for the reasons set forth above, the claims still are rejected since the symptoms of the disorder manifest before administering the composition and then require the treatment, thus the disorders are in fact not prevented rather they are treated.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 6, 8, 10, and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claims 6 and 8 recite "sodium hydrogen" which is indefinite since it is unclear what exactly is being claimed by the applicant. Further clarification is requested. Is applicant claiming sodium hydrogen carbonate? If this is the case applicant is requested to recite the full name of the compound.

Claim 21 recites "the method of claim..." however the claim is not indicated. Therefore, this claim is indefinite since it is unclear what claim 21 is depending on.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 17-18, 21-22, 23, 25-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kennedy et al (6,165,445).**

Kennedy et al disclose a pharmaceutical composition containing 0.25%-5% tyloxapol and a carrier medium (distilled water/saline) for the treatment of respiratory diseases and distress. Kennedy discloses the prior art Alevaire formulation containing 0.125% tyloxapol, 2% NaHCO3, and 5% glycerol. See example 6. Kennedy discloses the prior art's use of the compositions containing tyloxapol for mucus secretion, chronic bronchitis, and respiratory disorders. See Background section. Kennedy's formulation removes the side effects caused by the prior art by eliminating DPPC and using low concentrations of NaHCO3. See column 7, lines 43-45, column 11, lines 19-21, and column 21, lines 5-11. Table 1 discloses a range of tyloxapol concentrations including 0.1 mg/ml, 1 mg/ml, and 10 mg/ml. Kennedy discloses administering the composition by aerosolization using a positive pressure nebulizer to produce particle size of less than 5 microns. See column 10, lines 65-67. For administration of nasal airway for relief of nasal rhinitis or rhinosinusitis, the tyloxapol solution is administered in the form of a fine spray from a squeeze bottle. See column 12, lines 1-10. The reference discloses a tyloxapol formulation for asthma. See column 19, lines 25-30.

***Response to Arguments***

Applicant argues that Kennedy et al is directed to respiratory disorders, particularly asthma, inflammation and rhinitis. It is argued that these disorders are not connected to snoring, SIDS, sleep apnea, or improvement of nasal breathing.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner points out that the claims rejected are directed to the method of for improving nasal breathing and the device claims. Thus, Kennedy teaches treating respiratory disorders; i.e. asthma, bronchitis, rhinitis, which effect breathing conditions. Therefore, by alleviating these conditions, improvement of nasal breathing is inherently provided for. The recitation of "improving nasal breathing" is a broad method claim that reads on any disorder that affects the nasal passages. For instant, rhinitis, referred to as the common cold, blocks nasal passages and thus by treating the common cold, one inherently improves breathing. In regards to asthma, in this disorder, an individual has episodes of breathlessness, wheezing, and coughing whereby nasal breathing is reduced. By treating asthma, one inherently increases the breathing capacity in the nasal passages. Secondly, it is pointed out that claim 18 recites "improvement of nasal breathing impaired due to a disease, infection, or surgery". Therefore, the applicant's argument is not understood since asthma, the common cold (rhinitis), and inflammation are diseases that impair nasal breathing.

Applicant argues that Kennedy discloses a composition with tyloxapol in the amount of 0.125 to 5% with no phospholipids and NaHCO3. It is argued that the prior art's Alevaire caused severe side effects and utilizes for streptomycin. It is further argued that Alevaire contains less tyloxapol compared to the instant invention and the composition is not utilized for snoring, sleep apnea, SIDS, or nasal breathing.

Firstly, the examiner points out that claims that the intended use of a product does not hold patentable weight in product claims. A recitation of the intended use of

the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Secondly, the examiner points out that the rejected claims only require 2 to 200 mg of tyloxapol with excipients. It is pointed out that the recitation of 2 to 200 mg does not have substantial weight since the applicant has not recited how much the entire composition contains and this amount is relative to the entire composition. For instance, if the excipient is in the amount of 400 mg and the tyloxapol is in the amount of 2 mg, this is relatively low amount of tyloxapol. In regards to applicant's argument that the instant invention contains high concentration of tyloxapol, Kennedy clearly discloses a composition with high concentrations of tyloxapol in a carrier medium. Note abstract. Furthermore, Kennedy teaches in Table 1 10 mg/ml of tyloxapol, which is instant amount.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 19-20 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy et al (5,849,263).**

Kennedy et al disclose a pharmaceutical composition containing 0.25%-5% tyloxapol and a carrier medium (distilled water/saline) for the treatment of respiratory diseases and distress. Kennedy discloses the prior art Alevaire formulation containing 0.125% tyloxapol, 2% NaHCO3, and 5% glycerol. See example 6. Kennedy discloses the prior art's use of the compositions containing tyloxapol for mucus secretion, chronic bronchitis, and respiratory disorders. See Background section. Kennedy's formulation removes the side effects caused by the prior art by eliminating DPPC and using low concentrations of NaHCO3. See column 7, lines 43-45, column 11, lines 19-21, and column 21, lines 5-11. Table 1 discloses a range of tyloxapol concentrations including 0.1 mg/ml, 1 mg/ml, and 10 mg/ml. Kennedy discloses administering the composition by aerosolization using a positive pressure nebulizer to produce particle size of less than 5 microns. See column 10, lines 65-67. For administration of nasal airway for relief of nasal rhinitis or rhinosinusitis, the tyloxapol solution is administered in the form of a fine

spray from a squeeze bottle. See column 12, lines 1-10. The reference discloses a tyloxapol formulation for asthma. See column 19, lines 25-30.

Kennedy does not specify the type of physical activity. Kennedy does not specify a dry powder inhaler.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to treat nasal breathing due to physical activity. One would be motivated to do so since Kennedy teaches the treatment of nasal breathing, i.e. asthma or rhinitis. Therefore, one would expect similar results in improving breathing due to another cause. Furthermore, since Kennedy et al teach the use of the tyloxapol composition for asthma and asthma may be caused by physical duress and activities such as hiking and climbing that cause the duress, the treatment of asthma will implicitly improve breathing during physical activities. Lastly, the source per se of problems with nasal breathing does not impart patentable distinction unless it imputes a different characteristic from that known in the art.

It is deemed obvious to one of ordinary skill in the art to utilize the appropriate dosage form such as a dry powder inhaler. One would be motivated to do so depending on the symptom to be treated and the desired effect of the composition.

***Response to Arguments***

Applicant argues that Kennedy points away from the instant invention since it is intended for a different purpose. It is argued that Kennedy teaches the composition for inflammatory disorders and intentionally avoids sodium bicarbonate and phospholipids. Applicant argues that Kennedy's particle size is less than instant size.

Applicant's arguments have been fully considered but they are not persuasive. The claims that have been rejected in the instant obviousness rejection neither recite a particle range nor glycerol or sodium bicarbonate. Thus, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). for arguendo sake though, the examiner points out that Kennedy teaches both pulmonary and nasal administration. Note column 11 and 12.

Secondly, since Kennedy et al teach the method of treating asthma with tyloxapol and it is known in the art that certain physical activities such as instant hiking, climbing, etc, cause an asthmatic episode that reduces breathing capacity, the treatment of asthma implicitly treats improvement of nasal breathing during physical activity.

**Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy et al (5,849,263) or in view of Meyer et al (5,958,902) in further view of Alfonso et al (6,017,963).**

Kennedy et al disclose a pharmaceutical composition containing 0.25%-5% tyloxapol and a carrier medium (distilled water/saline) for the treatment of respiratory diseases and distress. See column 7, lines 43-45 and column 11, lines 19-21. Kennedy discloses the Alevaire formulation containing 0.125% tyloxapol, 2% NaHCO3, and 5% glycerol. See example 6. Kennedy teaches the utilization of EXOSURF for neonatal RDS and the dosage. Kennedy discloses that the application of EXOSRUF, which

contains other ingredients besides tyloxapol, was noted with side effects. See column 6, lines 3-41. Kennedy teaches the utilization of the tyloxapol alone for conventional applications in the art but without the side effects of the other ingredients such as DPPC. Kennedy teaches the without the use of hypertonic agents or other active ingredients (DPPC), one can derive higher concentration of tyloxapol for less and frequent and more rapid administration. Further this increases tyloxapol's benefits such as its reduced toxicity and enhanced half-life, while avoiding the side effects associated with other ingredients. See column 8, lines 29-42.

Kennedy does not specify all the instant respiratory diseases. Kennedy does not teach instant particle sizes.

Meyer teaches the application of a lung surfactant to the reduce sleep apnea and snoring. The lung surfactant is EXOSURF. See column 4, lines 50-54. The composition is administered nasally or orally (pharyngeal region). Meyer teaches the use of several devices to deliver nasal compositions with instant attachments. For instance a tapered extension nozzle for direct application to the pharyngeal region. See column 5, lines 42-50. The composition is administered before bed. Note examples.

Alfonso et al teach formulations for intranasal administration. Alfonso et al teach that the composition is housed in any dosage form for oral or nasal insufflation. The reference states that generally inhalation devices comprise a housing having a passageway for the flow of air, in which one end is inserted into the mouth or nose. The average particle size is from 0.1 to 10 microns for oro-pulmonary route and 10 to 355 micron for the nasal route. See column 7, lines 2-16.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Kennedy et al and Meyer et al and utilize Kennedy's composition to treat sleep apnea and infant death syndrome (SIDS). One would be motivated to do so since Meyers teaches EXOSURF to treat sleep apnea and snoring. Therefore, since Kennedy teaches the use of an improved tyloxapol composition, in place of the prior art EXOSURF since it eliminates the side effects associated with EXOSURF and yet treats the disorders that EXOSURF is used for, one would also expect the similar results by utilizing Kennedy's formulation to treat sleep apnea and snoring. Further, one would expect to treat infant death syndrome, which is the cessation of respiration while an infant sleeps, since this disorder falls under the scope of sleep apnea. Therefore, it is prima facie obvious to use Kennedy's improved formulation for all prior art applications of EXOSURF since Kennedy teaches the application of his improved formulation for all prior applications of EXOSURF.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Kennedy et al, Meyer et al, and Alfonso et al and utilize the instant particle size. One would be motivated to do so since Alfonso et al teach the instant particle range for both naso-pharynx and pulmonary tract administration in conventional inhalation devices. Therefore, one would be motivated to utilize the appropriate particle size depending on the disorder to be treated and the location to be treated, i.e. nasal administration requires bigger particles than the administration to the pulmonary region.

Lastly, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to manipulate the concentration of the prior art's formulation through routine experimentation. Differences in concentrations do not impart patentability for subject matter encompassed by the prior art unless an indication of criticality is shown. One would be motivated to do so since Kennedy provides the general parameters of the formulation and manipulation is based on the desired pH, isotonicity, etc.

***Response to Arguments***

Applicant argues that Kennedy teaches a formulation devoid of other compounds and Meyer teaches EXOSURF, which contains phospholipids and tyloxapol. Applicant states that EXOSURF is not the same as instant composition.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that Kennedy et al also disclose the instant composition for general treatment of respiratory disease. It is further pointed out that snoring, SIDS, and sleep apnea are all related to respiratory disorders. Secondly, it is pointed out that Kennedy teaches that the inventive formulation is utilized in place of the prior art EXOSURF and all the methods EXOSURF is utilized for. Thus. although Kennedy does not specify sleep apnea and snoring, with the combined teaching of Kennedy 's improved composition and utilizing it to replace EXOSURF and the methods in which EXOSURF is used and Meyer's teaching of EXOSURF for snoring and sleep apnea, it is prima facie obvious to utilize the Kennedy's composition for treating sleep apnea and snoring.

Applicant argues that there is not motivation to manipulate the concentrations.

In regards to claims 8 and 10, firstly the composition of ALEVAIRE is cited to demonstrate the composition containing tyloxapol, sodium bicarbonate, and glycerol is well known in the art. Although, Kennedy teaches away from ALEVAIRE, the examiner points out that "the use of patents as references is not limited to what the patentees describe as their own invention or to the problems with which they are concerned with. They are part of the literature of the art, relevant for all they contain." See In re Heck. The only difference between the instant invention and ALEVAIRE is that it has increased amount of tyloxapol. The motivation to increase the concentration of this agent comes from Kennedy who teaches an increased amount of tyloxapol and decreased concentration of excipients. Further, it is pointed out that Kennedy et al teach reduced hypertonicity by eliminating *significant* concentration of NaHCO3. See abstract. Thus, Kennedy does suggest the formulation can contain a hypertonic agent, however it must be in low concentrations. Furthermore, from this teaching the art clearly provides a motivation to manipulate the amounts contained in the prior art formulation of ALEVAIRE itself to provide for a better formulation without the side effects experienced by prior art formulations. Lastly, the applicant has not established the criticality of the instant amount of excipients since Kennedy effectively demonstrates that his improved formulation with less concentration of sodium bicarbonate can replace and effectively treat all the instant conditions and eliminate the side effects associated with the instant excipients.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG

MICHAEL G. HARTLEY
PRIMARY EXAMINER